

REMARKS

Claims 10, 15, 32 and 36-38 are pending in the application, the remaining claims being canceled as directed to subject matter not elected after a restriction requirement.

Interview

An interview was conducted with the Examiner on October 18, 2008. The substance of the interview related to the Examiner's interpretation of the phrase, "comprising the steps of...", and the scope of the prior art of record.

In particular, Applicants' Representative urged that the phrase "comprising the steps of" is open to inclusion of further steps, but that any particular step described in the claims is limited to the elements recited. To interpret the claims otherwise would be to vitiate the limitations present in the claims. The Examiner acknowledged Applicants' position and agreed to reconsider her position once Applicants' presented the argument in writing.

Applicants' Representative also presented their position that Gabathuler and Jefferies each disclose only conjugates of p97 with a therapeutic moiety. The Examiner agreed this was the case for Gabathuler, and agreed to review whether this was also true of Jefferies. The Examiner further agreed that, as to a "radiolabelled" protein, such would indeed be considered a conjugate.

Objection to claim 14

Claim 14 is objected to as having an incorrect status identifier. This is corrected in this paper.

Rejections over prior art

Claims 32 and 36-38 are rejected under 35 USC § 102(b) as anticipated by Gabathuler. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As discussed in the interview, Gabathuler discloses only p97 proteins that are conjugated, *i.e.*, covalently attached, to some other therapeutic moiety. The Examiner agreed with this interpretation of Gabathuler during the interview. In the present invention, there is no such conjugation to the p97 protein.

The Examiner's position is that the "comprising" language in claim 32 provides inclusion of additional elements to the claim. As explained in the interview, at least in this instance, such an interpretation is not reasonable, as it completely vitiates the recited limitations in the claims.

It is true that the claim term "comprising" is "open" and therefore the composition as recited might include additional ingredients. Thus, an additional compound, or a salt, or the like, could be included in the claimed pharmaceutical composition. However, the claim is not "open" with respect to the arrangement of the ingredients stated, which must be respected in regard to the remaining language of the claim at issue. To otherwise interpret the claim is to vitiate limitations recited in the claims.

In the present instance, the claim recites a soluble p97 or fragment thereof. There is no mention at all of any covalent attachment to any other substance, and to read the claim as possibly including such is to introduce into the invention an aspect not contemplated by the inventors. Applicants note that the specification does not include any reference to p97 covalently attached to any kind of another molecule.

Accordingly, the present claims 32 and 36-38 must be read as excluding conjugates of p97 to another therapeutic moiety, and so distinct from what is described by Gabathuler. Therefore, Gabathuler does not anticipate claim 32, and this rejection must be withdrawn.

Claims 10, 14, 15, 32 and 36-38 are rejected under 35 USC § 102(e) as unpatentable over Jefferies '494. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Jefferies, like Gabathuler, only describes therapeutic uses of p97 for treating cancer in the context of a conjugate to another therapeutic moiety. The Examiner might refer to columns 28-29 of the reference, which appears to be where this aspect of Jefferies invention is disclosed.

So as to advance the present prosecution, the claims have been amended to recite only the subject matter elected following restriction, *i.e.*, to compositions and methods utilizing unconjugated p97 as an active ingredient.

For all of the reasons explained above, Jefferies' disclosure is distinct from what is presently claimed as Applicants' invention. Accordingly, the instant rejection should be withdrawn.

Applicants submit that the present application claims subject matter patentable over the prior art of record. The favorable actions of withdrawal of the standing rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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